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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/381,747	09/22/99	TORMO	M UTSC:550---/

HM12/0828

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EXAMINER	
LACOURCIERE,K	
ART UNIT	**PAPER NUMBER**
1635	14

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/381,747	Tormo et al.
Examiner	**Art Unit**
Karen A. Lacourciere	1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Aug 1, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: The amendment to claim 24 is improper as marked up copy does not reflect the insertion of the word "composition". Further, claims 24 and 25 are drawn to a composition and method not previously considered.

4. ☒ Applicant's reply has overcome the following rejection(s):
   Please see attached.

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   Applicant's declaration has overcome the Tormo et al. reference, however, the claims are rejected under 35 USC 112, first paragraph and Obviousness type Double Patenting (please see attached).

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
   Claim(s) allowed: _____
   Claim(s) objected to: _____
   Claim(s) rejected: *1-49*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. ☐ Other:
    please see attached.

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER

Applicant has not overcome the objection to the declaration set forth in the prior Office actions (mailed 7-10-00 and 02-01-01). The substitute declaration submitted on 08-01-01 is still not proper, as inventor Tormo has not signed the declaration.

Applicant has not overcome the provisional Double Patenting rejection based on copending application 08/726,211 set forth in the prior Office action (mailed 02-01-01) as the rejected claims are still pending in both Applications.

Applicant has not overcome the obviousness type Double Patenting rejection of claims 1-9 and 21-38 over U.S. Patent No.'s 5,855,911 and 6,042,846. Applicant has demonstrated that the reference Tormo et al. is not available as prior art with the Declaration submitted 08-01-01, however, the instantly claimed compositions would still be an obvious species of the claims of U.S. Patent No.'s 5,855,911 and 6,042,846 in view of Evan or Green or Reed alone.

Applicant has overcome the rejection of record of claims 1-9 and 21-38 under 35 USC 103(a) by submission of the declaration filed 08-01-01.

Applicant has not overcome the rejection of record of claims 10-20 and 39-49 under 35 USC 112, first paragraph, set forth in the prior Office action (mailed 02-01-01). Applicant argues that the examiner has not provided any evidence to negate Applicant's assertion that the invention is enabled. This is not found to be persuasive because the rejection of record provides references which teach the unpredictability of antisense and support the unpredictability of mouse models for delivery of antisense in humans. Applicant argues that the affidavits submitted in response to the

Office action mailed 07-10-00 support the correlation of mouse models with human results, however, the evidence submitted by Applicant is directed to the use of small molecules in mouse models, which is not directed to the scope of the instant claims, which are drawn to antisense.

Applicant has overcome the rejection of record of Claim 36 under 35 USC 112, second paragraph.